WO 2005/071069 32 PCT/EP2005/000695

## **CLAIMS**

1. A chimeric empty capsid of the infectious bursal disease virus (IBDV), characterized in that it is constituted by assembly of (i) IBDV pVP2 proteins and (ii) fusion proteins comprising a region A constituted by the IBDV VP3 protein bound to a region B constituted by a heterologous polypeptide comprising a polypeptide of interest.

5

10

25

- 2. Capsid according to claim 1, wherein said region B is bound to the amino-terminal region of IBDV VP3, or alternatively to the carboxy-terminal region of IBDV VP3.
- 3. Capsid according to claim 1, wherein said polypeptide of interest is a polypeptide useful in vaccination, therapy or diagnosis.
- 4. Capsid according to claim 1, wherein said region B comprises a single polypeptide of interest.
  - 5. Capsid according to claim 1, wherein said region B comprises two or more polypeptides of interest.
- 20 6. Capsid according to claim 1, wherein said fusion protein comprises a region A bound to a single region B.
  - 7. Capsid according to claim 1, wherein said fusion protein comprises a region A bound to two regions B, equal or different, one of them bound to the amino-terminal region of VP3 present in region A, and the other one to the carboxy-terminal region of VP3 present in region A.
  - 8. Capsid according to claim 7, wherein said regions B contain more than one polypeptides of interest equal to or different from one another.
  - 9. Capsid according to claim 1, wherein said fusion protein further comprises, a linker polypeptide located between said regions A and B.

WO 2005/071069 33 PCT/EP2005/000695

10. A nucleic acid, said nucleic acid having a nucleotide sequence which comprises the nucleotide sequence encoding for the fusion protein defined in anyone of claims 1 to 9.

- 11. A nucleic acid, said nucleic acid having a nucleotide sequence which comprises
  5 (i) a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP3 protein and (ii) a nucleotide sequence comprising the open reading frame of one or more heterologous polypeptides comprising one or more polypeptides of interest.
- 12. Nucleic acid according to claim 11, further comprising (iii) a nucleotide sequence comprising the open reading frame corresponding to the IBDV pVP2 protein.
  - 13. A gene construct comprising a nucleic acid according to claim 10 or 11.
  - 14. A gene construct comprising a nucleic acid according to claim 12.

15

- 15. An expression system selected from:
- a) an expression system comprising a first gene construct according to claim 13, operatively bound to transcription, and optionally translation, control elements, and a second gene construct, operatively bound to transcription, and optionally translation, control elements; said second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV pVP2 protein; and
- b) an expression system comprising a gene construct according to claim 14, operatively bound to transcription, and optionally translation, control elements.
- 16. Expression system according to claim 15, said expression system being selected from plasmids, bacmids, yeast artificial chromosomes (YACs), bacteria artificial chromosomes (BACs), bacteriophage P1-based artificial chromosomes (PACs), cosmids, or viruses, which optionally contain a heterologous replication origin.
- 30 17. A host cell containing a nucleic acid according to anyone of claims 10 to 12, or a gene construct according to anyon of claims 13 or 14, or an expression system according to anyone of claims 15 or 16.

WO 2005/071069 34 PCT/EP2005/000695

- 18. A host cell, said cell having been transformed, transfected or infected with an expression system according to any of claims 15 or 16.
- 19. Host cell according to claim 17 or 18, said cell being selected from a mammal cell, an avian cell, an insect cell and a yeast.
  - 20. A process for the production of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9, comprising culturing a host cell according to anyone of claims 17 to 19, and, if desired, recovering said chimeric empty IBDV capsids.
  - 21. Process according to claim 20, wherein said host cell is an insect cell, comprising the steps of:
- a) preparing an expression system selected from (I) and (II), wherein:

10

- expression system (I) is constituted by a recombinant baculovirus containing a gene construct according to claim 14; and
- expression system (II) is constituted by a first recombinant baculovirus containing a gene construct encoding for the IBDV pVP2 protein, and a second recombinant baculovirus containing a gene construct according to claim 13;
- b) infecting insect cells with said expression system prepared in step a);
  - c) culturing the infected insect cells obtained in step b) under conditions allowing the expression of recombinant proteins and their assembly to form chimeric empty IBDV capsids; and
  - d) if desired, isolating and optionally purifying the chimeric empty IBDV capsids.

WO 2005/071069 35 PCT/EP2005/000695

- 22. A process according to claim 20, wherein said host cell is a yeast, comprising the steps of:
- a) preparing an expression system constituted by a plasmid containing a gene construct according to claim 14;

5

- b) transforming yeast cells with said expression system prepared in step a);
- c) culturing the transformed yeasts obtained in step b) under conditions allowing the
  expression of recombinant proteins and their assembly to form chimeric empty
  IBDV capsids; and
  - d) if desired, isolating and optionally purifying the chimeric empty IBDV capsids.
- 23. The use of a gene expression system according to anyone of claims 15 or 16 for producing chimeric empty IBDV capsids according to anyone of claims 1 to 9.
  - 24. The use of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9 in the manufacture of a medicament.
    - 25. Use according to claim 24, wherein said medicament is a vaccine.
    - 26. Use according to claim 24, wherein said medicament is a gene therapy vector.
- 27. A vaccine comprising a therapeutically effective amount of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9, optionally together with one or more pharmaceutically acceptable adjuvants and/or vehicles.
- 28. A vaccine according to claim 27, useful to simultaneously protect animals or humans against infection caused by two or more disease-causing infectious agents.
  - 29. A gene therapy vector comprising a chimeric empty capsid of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9.